

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bauer et al.

Application No. 10/686,548

Filed: October 14, 2003

Confirmation No. 3478

For: POSITIVE DETECTION LATERAL-
FLOW APPARATUS AND METHOD FOR
SMALL AND LARGE ANALYTES

Examiner: Gary W. Counts

Art Unit: 1641

Attorney Reference No. 6122-66637-01



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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this request, although a Terminal Disclaimer has been filed on December 2, 2005, to overcome the obviousness-type double patenting rejection. Claims 22-30 were also cancelled in the December 2, 2005, amendment which leaves for consideration only claim 1 and its dependent claims 2-21, 31, 35-38, 40-45, 47, and 49.

The Claimed Invention

The claimed invention (as shown for example in FIG. 1) concerns a lateral flow test strip 22 having a sample application area 32, a mobilization zone 54, a primary capture area 50 and a secondary capture area 52 spaced in a direction of liquid flow 38 along the test strip. A detectable tracer (A-L-T) is present in mobilization zone 54, and as noted in claim 1 "the detectable tracer is present on the test strip in a position that a distal flow of analyte reaches the

primary capture area before a distal flow of tracer reaches the primary capture area.” This claimed placement of the detectable tracer allows the unlabelled analyte to reach the primary capture zone 50 and occupy its binding sites before the detectable tracer reaches the primary capture zone, so that the detectable tracer continues along the path of flow distally to the secondary capture zone 52.¹

An advantage of the claimed combination is that it provides greater sensitivity of the assay because the labeled analyte more readily passes through the occupied primary capture zone to provide a signal in the secondary capture zone that indicates a presence (and/or semi-quantitative amount) of the analyte in the sample.

The Rejection

The Office actions cited Boehringer et al. (WO 98/39657) as rendering the claimed invention obvious because that reference shows a sample application area 12, a labeling zone 14, and multiple capture lines 16a, 16b and 16c. The examiner contends that Boehringer et al. uses a latex particle coated with BSA, which is similar to the materials used by applicant and that the prior art device therefore satisfies the limitations of claim 1.²

Applicants have submitted the Declaration of Buck which demonstrates that Boehringer et al. does not necessarily disclose the claimed invention. That Declaration shows that the position of the detectable tracer on the test strip (as required by claim 1) determines whether the claimed differential separation of the analyte and detectable tracer occurs. For example, the Declaration of Buck shows that the distance between the placement of the detectable tracer and the primary capture zone can determine whether the liquid wave fronts that carry the analyte and the detectable tracer have time to separate before reaching the primary capture zone. Applicants’ specification discloses a number of ways for the detectable tracer to be “present on the test strip in a position” to achieve the differential flow of the detectable tracer and analyte.³ The October 18, 2005 Advisory Action agrees that it is “proven in the Declaration of Buck submitted with Applicants’ prior response [that] it is quite possible for the detectable tracer and analyte to reach the primary capture zone together for example if the detectable tracer does not migrate a distance sufficient for separation of the wave fronts to occur.”

¹ See claim 1.

² Final Office action, October 18, 2005, page 3.

³ See Applicants’ Amendment and Response After Final Action, footnote 1 on page 11.

MPEP 2112 states that the standard for establishing a § 102/103 rejection based on inherency is that any missing descriptive matter is “necessarily present” and that inherency “may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient” to maintain the rejection.⁴ The Advisory Action agrees that it is possible that Boehringer et al. does not achieve differential separation of the wave fronts carrying the analyte and detectable tracer, as claimed. However the inherency rejection was still maintained because “the declaration is not commensurate with the scope of the claims.”⁵ In other words, the claim does not specifically recite that the differential tracer is placed on the test strip at a distance from the primary capture zone that allows the wave front separation to occur.

Claims 1-21

Applicants submit the inherency rejection in view of Boehringer et al. is clear error with respect to claim 1 because it overlooks claim limitations and inverts the proper burden of proof. One claim limitation that is overlooked in claim 1 is that the “detectable tracer is present on the test strip in a position that a distal flow of analyte reaches the primary capture area before a distal flow of tracer.”⁶ This claim limitation clearly includes placing the tracer and primary capture zone at a sufficient distance from each other to allow separation of the wave fronts, but it is also broad enough to include alternative positions that achieve this claimed separation, such as placement of the tracer deep in the test strip or under the sample application area (see FIG. 2). The claim therefore includes language that makes it consistent with the declaration evidence that has been submitted, and claim 1 is allowable. The examiner’s contention that no structural features have been recited is not accurate because that contention overlooks the language of the claim that specifically addresses placement of the detectable tracer on the test strip that allows the analyte to reach the primary capture zone first.

The Advisory Action also appears to incorrectly conflate the requirements of showing unexpected results and the requirements for showing that Boehringer et al. does not necessarily disclose the claimed invention. The Advisory Action states that “Applicant has not shown why

⁴ More extensive discussion of this point is present in the Response After Final Action at page 12.

⁵ October 18, 2005 Advisory Action, page 3, lines 5-6.

⁶ Claim 1, lines 13-14.

the distance of the tracer zone from the primary capture zone of the current application is better than that of Boehringer et al.”⁷ However there is no requirement for making such a showing. The Declaration of Buck was submitted to show that the differential separation of wave fronts does not necessarily occur and that Boehringer et al. therefore does not inherently disclose the invention. There is no need to demonstrate superiority of the claimed invention, as apparently required in the Advisory Action. However even if there were such a requirement it should be noted that the Declaration of Buck does address the increased sensitivity that is obtained by differential migration of the analyte and detectable tracer, and it concludes that differential migration increases sensitivity of the test.⁸

Once it is recognized that Boehringer et al. does not establish a prima facie case of obviousness of the invention as claimed, in which the detectable tracer is “present on the test strip in a position” that the differential migration occurs, claim 1 and its dependent claims 2-21 should be allowable. Boehringer et al. is cited either alone or in combination with other references to reject all these claims.

Claims 31, 35-38, 40-45, 47 and 49

Claims 31, 35-38, 40-45, 47 and 49 depend from claim 1 and are allowable for the reasons set forth above in connection with claim 1.

⁷ Advisory Action, page 3, lines 7-8.

⁸ Declaration of Buck, page 2, lines 4-6.

Conclusion

The incorrect application of the requirements for establishing inherency, as set forth in MPEP 2112, constitutes a clear error that should result in the allowance of the pending claims.

Respectfully submitted,

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